PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Anne M. Pianca et al.	**Confirmation No.:**	3029
Serial No.:	10/081,457	**Examiner:**	G. Evanisko
Filed:	02/21/2002	**Art Unit:**	3762
Docket No.:	98P1021US08		
For:	SELF-ANCHORING CORONARY SINUS LEAD		

DECLARATION UNDER 37 C.F.R. §1.132 TO TRAVERSE A REJECTION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
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P.O. Box 1450
Alexandria, VA 22313-1450, on:

December 8, 2005

Estella Pineiro — 12/8/05
Date

Sir:

I, David E. Kistler, declare that:

1) I am the Marketing Director of implantable leads for Pacesetter Inc., the assignee of the above identified application.

2) Pacesetter's QuickSite® left ventricular lead, which is covered by the claims of the subject application (see product specification in attached **Exhibit A)**, has enjoyed considerable success in the marketplace for cardiac resynchronization therapy (CRT) leads. Cardiac resynchronization therapy, as a treatment for heart failure has gained significant acceptance in the medical field.

3) To provide left side stimulation and sensing, leads are transvenously implanted in the coronary sinus region, for example, in a vein such as the great vein or the left posterior ventricular vein or other coronary veins proximate the left ventricle of the heart. Such placement avoids the risks associated with implanting a lead directly within the left ventricle, which is a difficult and unproven procedure. The implantation of

a lead in the coronary sinus region is often difficult, however, because of the extreme curvatures in the coronary vessels, their narrowness, anomalies in the vascular anatomy because of disease, and the number of veins which may communicate with the desired lead feed path. The difficulty of this procedure has traditionally resulted in relatively long implant times and relatively low implant success rates. In addition adequate fixation of leads in a coronary vessel is difficult to achieve.

4) The QuickSite® left ventricular lead has met a long felt need for a stable left side heart lead with improved handling that was both persistent and that was recognized by those of ordinary skill in the art. For example, the QuickSite lead provides improved stability and fixation over other currently available left heart leads. The S-shaped distal end of the QuickSite lead, as recited in the claims of the subject application, can be anchored in both large and small veins allowing the lead to be placed in a site that provides high performance while also reducing/minimizing extracardiac stimulation such as phrenic nerve stimulation, which is common in the Easytrak® left heart lead manufactured by Guidant Corporation. Further, the stability of the QuickSite lead is demonstrated by its exceptionally low dislodgement rate compared to the left heart lead of Pacesetter's primary competitors, namely the Guidant Easytrak lead and the Attain® model 4193 and 4194 left heart leads, manufactured and sold by Medtronic, Inc. For example, the QuickSite lead dislodgement rate is approximately 50% less than the dislodgement rate for the Attain lead and approximately 75% less that the Easytrak lead. (see **Exhibit B**). In addition, in the RHYTHM clinical trial the dislodgement rate for the QuickSite lead was less than 1% which is even lower than that reported in initial trials. Post implant lead dislodgements require a second surgical intervention to reposition/replace the dislodged lead. Therefore, the use of the QuickSite lead significantly reduces the number of secondary surgical procedures required for heart failure patients who oftentimes are in very poor health and at significant risk due to surgical complications.

5) In addition, Pacesetter's QuickSite lead which includes an S-shaped portion that forms a steerable canted end and the ability to use a stylet driven or over the wire implant technique as recited in the claims of the subject application, achieved a 94.4% implant success rate in the RHTYHM ICD clinical trial as shown on the attached clinical trial summary in **Exhibit C**). By way of comparison, Guidant reported in the Ventak CHF/Contak CD/Easytrak biventricular pacing study, that the Easytrak lead was successfully implanted in only 448 of 517 (86.7%) of the patients in whom an Easytrak lead implant was attempted (see page 14 of the attached Easytrak Physician's Manual in **Exhibit D**). In addition Medtronic reports an implant success rate of 93% in the news release announcing FDA approval of the model 4193 left heart lead (see **Exhibit E**). Improved implant success rate reduces the need for the implantation of external or epicardial leads which often require a mini thoracotomy or full sternotomy surgical procedure. Thoracic surgery, which typically involves the opening of the chest cavity to expose the patient's heart, can be highly traumatic to the patient. The trauma may be especially severe for those patients with congestive heart failure and typically also necessitates considerable in-hospital recovery time for the patient.

6) Pacesetter was third to market with the QuickSite lead. Even being third to market with the Quicksite lead, Pacesetter has grown total sales revenue from the QuickSite lead in the United States to over $45,000,000.00 since the introduction of the unipolar lead in June of 2004 and the bi-polar QuickSite lead in April of 2005. This growth in sales volume has allowed Pacesetter to capture approximately 15-20% of total market share for left heart vascular leads. The actual market share is not precisely known due to the lack of specific public disclosure of competitors' sales for cardiac resynchronization therapy leads and devices. The commercial success of this lead is directly derived from the invention as claimed in the subject patent application.

7) For example, the marketing material for the QuickSite lead stresses the superior handling and stability of the QuickSite lead as shown in the product marketing brochure in **Exhibit F**. It is because of these features that the QuickSite lead has been so commercially successful.

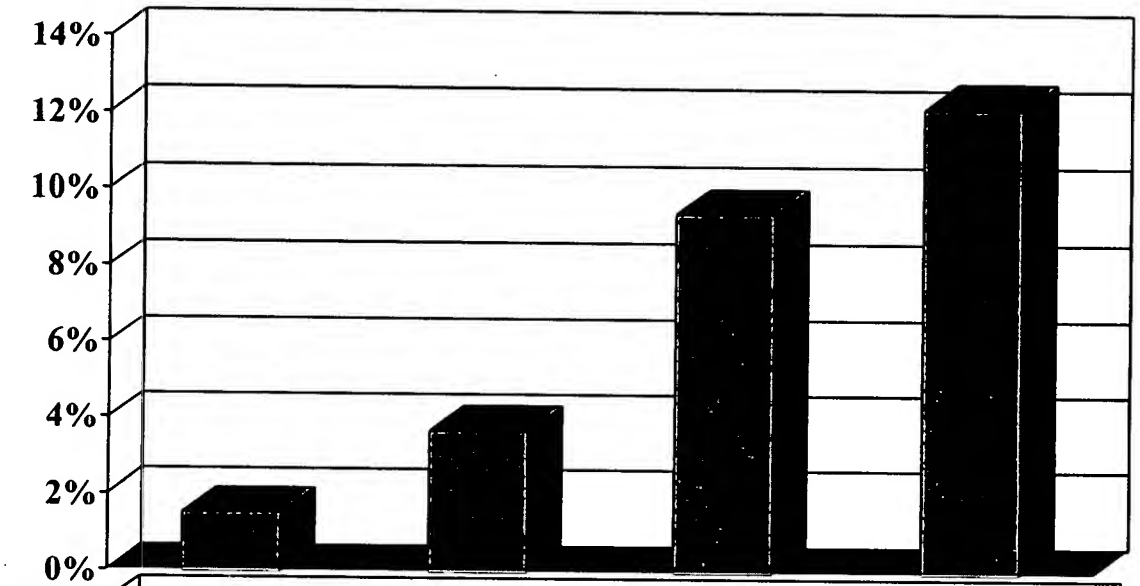
8) The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

December 8, 2005
Date

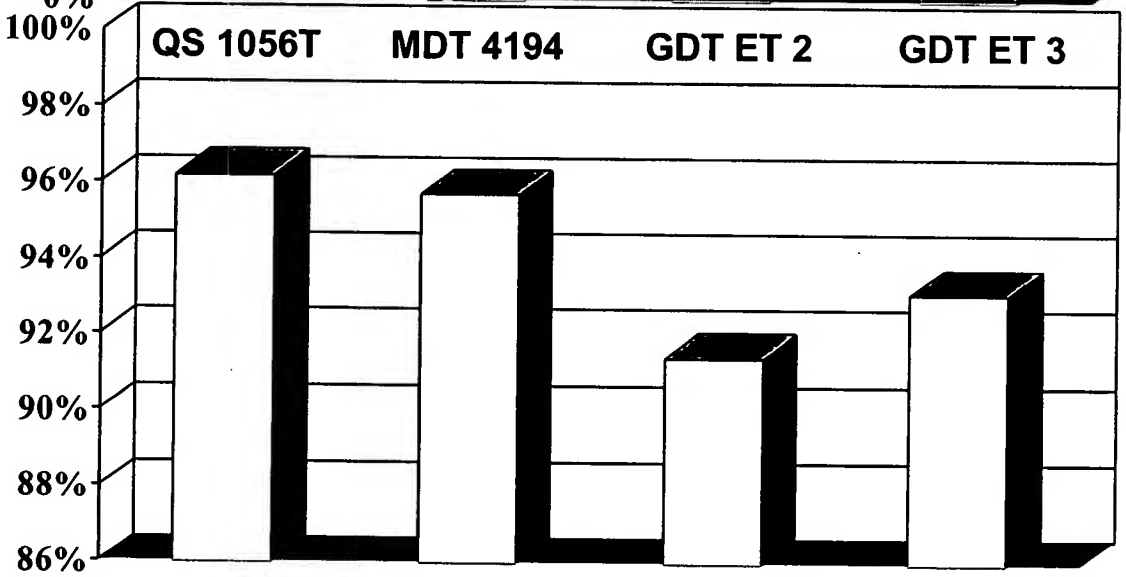
David E. Kistler
David E. Kistler

Note: These numbers came from different trials performed at different centers at different times.
Sources: St. Jude Medical QuickSite® Model 1056T User's Manual (data at three months)
Medtronic Attain® OTW 4194 Technical Manual (data post 3 months)
Guidant Easytrak® 2 Physician's Manual (data at 6 months)
Guidant Easytrak® 3 Physician's Manual (data at 6 months)

EXHIBIT B



Lead Dislodgement Rates



Freedom From LV Lead Related Complications

RHYTHM Clinical Results

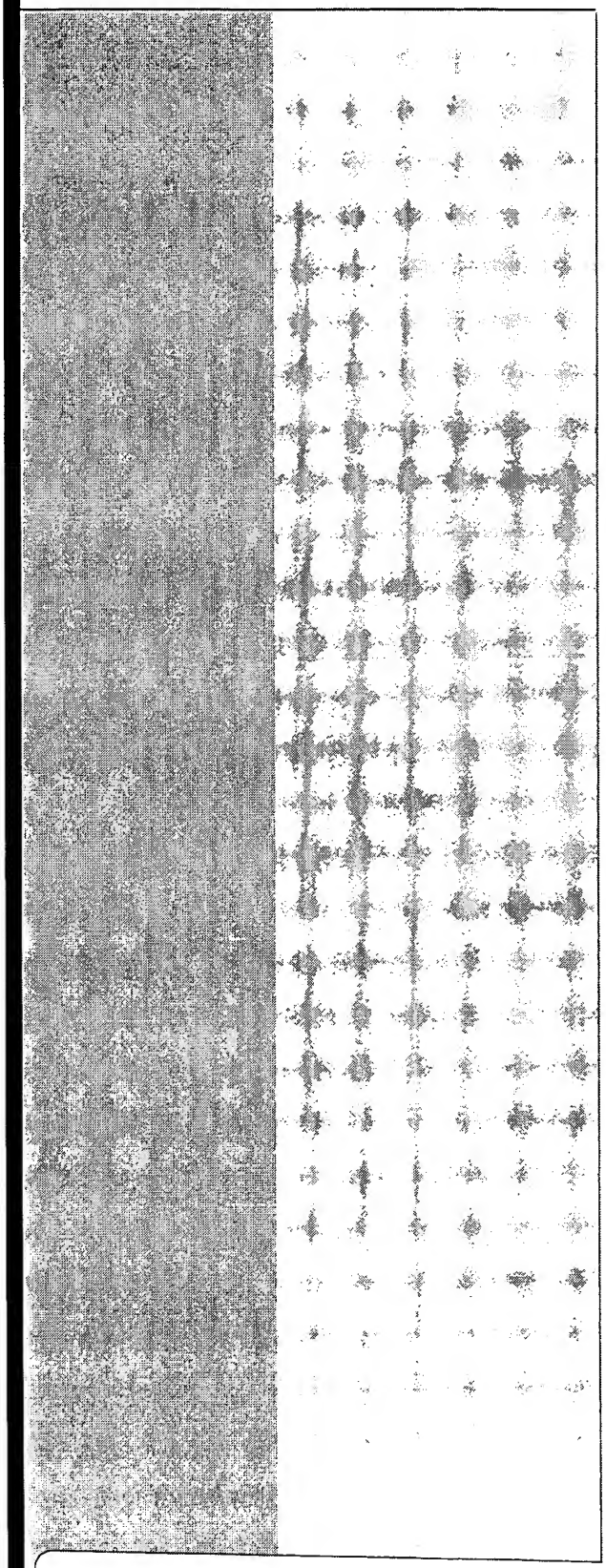
QuickSite® Study Results*

- 153 patients enrolled
- 94.4% implant success rate
- Only 1 dislodgement (<1% dislodgement rate)
- 1.6 V average capture thresholds
- 613Ω average lead impedance

*Results of the RHYTHM ICD/QuickSite lead study presented 3/9/04 in conjunction with the ACC Scientific Sessions

EXHIBIT C

Physician's Manual



EASYTRAK®

Coronary Venous
Steroid-Eluting Unipolar
Single Electrode
Pace/Sense Lead

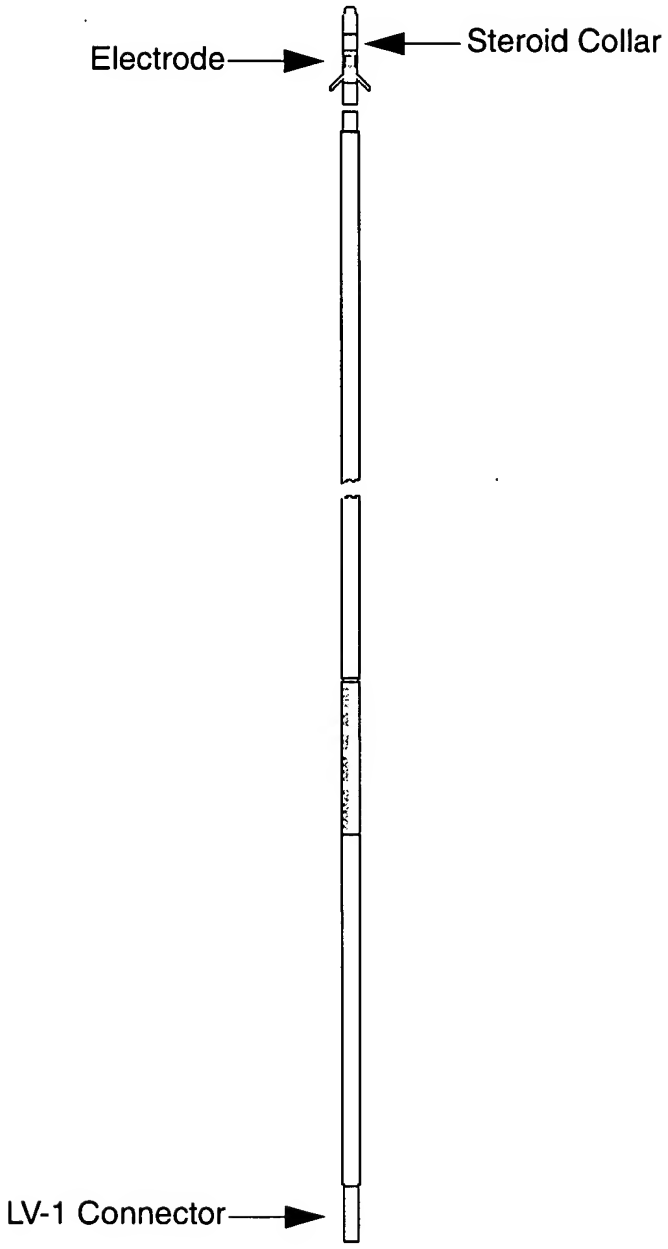
REF: 4510/4511/4512/4513

RESTRICTED DEVICE: Federal law (USA) restricts the sale, distribution, or use of this device to, by, or on the lawful order of a physician.

EXHIBIT D

GUIDANT

EASYTRAK® Lead
Models 4510/4511/4512/4513



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DEVICE DESCRIPTION

Guidant EASYTRAK® coronary venous, steroid-eluting, single-electrode pace/sense leads, Models 4510/4511/4512/4513, provide chronic pacing and sensing and are an over-the-wire design with a LV-1[1] connector. Placement is achieved by inserting the lead through the coronary sinus and placing it into a branch of the cardiac veins. The EASYTRAK lead is used in conjunction with a compatible Guidant cardiac resynchronization therapy (CRT) device.

Indications

The Guidant EASYTRAK coronary venous, steroid-eluting, single-electrode pace/sense leads, Models 4510/4511/4512/4513, are transvenous leads intended for chronic left ventricular pacing and sensing via the coronary veins when used in conjunction with a compatible Guidant cardiac resynchronization therapy (CRT) device that accepts the LV-1 connector.

Contraindications

Use of the EASYTRAK lead is contraindicated in patients with a hypersensitivity to a nominal single dose of 0.7 mg of dexamethasone acetate drug.

Warnings

- **Labeling knowledge.** Read this manual thoroughly before implanting the lead to avoid damage to the system. Such damage can result in injury to or death of the patient. Page 22
- When using a right ventricular (RV) pace/sense lead in conjunction with the EASYTRAK lead, it is recommended that a *polyurethane-insulated* lead be used. Failure to observe this warning could result in insulation damage of the RV lead, which can cause a periodic or continual loss of pacing, or sensing, or both.
- Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both.

- **Battery-powered equipment.** The use of battery-powered equipment is recommended during lead implantation and testing to protect against fibrillation that might be caused by leakage currents.

  -Line-powered equipment used in the vicinity of the patient must be properly grounded.

  -The lead connector must be insulated from any leakage currents that could arise from line-powered equipment.

- **Excessive flexing.** The lead is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, or lead dislodgment. Page 25
- If using a finishing wire accessory kit, use the corresponding finishing wire model for the lead length (Table 7). If the wrong length finishing wire is used, the finishing wire tip may extend out of the distal end of the lead or not stabilize the lead properly. Page 24

Precautions

In the following list of cautions, page numbers are indicated for those cautions that are specific to other areas of the manual. Refer to the indicated pages for information relevant to the caution. Failure to observe these cautions could result in incorrect lead implantation, lead damage/dislodgment, or harm to the patient.

Sterilization and Handling

- **For single use only—do not resterilize leads.** Do not resterilize the lead or the accessories packaged with it because Guidant cannot ensure that resterilization is effective. Do not reuse.
- **If package is damaged.** Guidant sterilizes the lead and accessories with ethylene oxide gas (EtO) before final packaging. When they are received, they are sterile and ready for use. If the container is wet, damaged, punctured, or if the seal is broken, return the lead to the nearest Guidant representative. Never attempt to resterilize the lead or accessories. Instead, return the lead to Guidant at the address on the back cover of this manual. Page 23

- **Use before date.** Do not implant the lead after the USE BEFORE date (which appears on the lead packaging) has passed because this date reflects a validated shelf life.
- **Lead compatibility.** Prior to implantation of this lead, confirm lead/pulse generator compatibility by calling Guidant Technical Services at the telephone number on the back cover of the manual.
- **Dexamethasone acetate.** It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of a low concentration, highly localized, controlled-release device. For a listing of potentially adverse effects, refer to the *Physician's Desk Reference*.
- **Defibrillating equipment.** Defibrillating equipment should be kept nearby for immediate use during the implantation procedure.

Lead Evaluation and Implantation Precautions

- **Vein pick.** The vein pick is not intended either for puncturing the vein or for dissecting tissue during a cutdown procedure. Page 24
- **Remove finishing wire.** The finishing wire MUST BE REMOVED before connecting the lead to the pulse generator. Page 25
- **Lead stabilizer.** Do not suture directly over the lead body, as this may cause structural damage. Use the suture sleeve to secure the lead at the venous entry site. Page 25
- **Do not wipe or immerse the distal lead tip in fluid prior to implant.** Such treatment will reduce the amount of steroid available when the lead is implanted. Page 25
- **Chronic repositioning.** Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted. Page 25
- **Protect from surface contamination.** The conductor insulation is silicone rubber, which can attract particulate matter, and therefore must always be protected from surface contamination. Page 25

- **Do not insert in medial one-third region of clavicle (subclavian puncture).** When attempting to implant the lead via a subclavian puncture, do not insert the lead under the medial one-third region of the clavicle. Damage or chronic dislodgment to the lead is possible if the lead is implanted in this manner. If implantation via the subclavian vein is desired, the lead must enter the subclavian vein near the lateral border of the first rib and must avoid penetrating the subclavius muscle. It is important to observe these implant precautions to avoid clavicle/first rib damage or chronic dislodgment to the lead. It has been established in the literature that lead fracture can be caused by lead entrapment in such soft tissue structures as the subclavius muscle, costocoracoid ligament, or the costoclavicular ligament. Page 26
- **Strain relief.** When implanting the lead via a subclavian puncture, allow slack in the lead between the suture sleeve and the venous entry site. This will help minimize flexing at the suture sleeve and interaction with the clavicle/first rib region. Page 28
- **Contrast medium.** Risks associated with this procedure are similar to any other catheterization procedure in the coronary sinus. Some patients can have a physical intolerance to different types of contrast agents. If this is known in advance, the physician should select an appropriate agent. Page 30
- **Balloon catheter use.** At the physician's discretion an occlusion balloon catheter may be used. Inflate the balloon to the recommended volume. Inject the contrast medium through the injection port to opacify the sinus and the distal venous branches. Immediately deflate the balloon after the venogram is obtained. Page 30
- **Contrast medium.** The type, amount, and rate of injection of the contrast medium must be determined by the physician's medical judgment regarding the adequacy of the venogram obtained. Page 31
- **Guide wire prolapse.** Use fluoroscopy to verify the guide wire does not prolapse and catch on the distal tip of the lead. If this occurs, slowly extend the wire beyond the distal

tip to free the guide wire and then retract it to reestablish movement of the guide wire. Page 32

- **Guide wire retraction.** If the guide wire cannot be retracted, withdraw the lead/guide wire assembly through the guiding catheter. Remove the guide wire through the distal tip of the lead and reintroduce the lead using a new guide wire. Follow the positioning procedures previously discussed. Page 32
- **Flushing a clotted lead.** Flushing a clotted lead can compromise lead integrity. If clotting is suspected, remove the lead from the body and soak the lead in heparinized saline. Insert a guide wire into the distal tip of the lead and advance the wire proximally through the terminal to clear clotting. If unsuccessful, use a new lead. Page 32
- **Applying tools to the distal end of the lead.** Applying tools to the distal end of the lead may result in lead damage. Page 32
- **Bending finishing wire.** Do not bend the finishing wire in the lead. Bends in the finishing wire could lock it in the lead or damage the conductor coil. Page 34
- **Remove finishing wire.** If the finishing wire cannot be retracted from the lead, withdraw the lead and finishing wire together. Do not implant with the finishing wire inside the lead. Page 34
- **Avoid too tight ligature.** When ligating the vein, avoid too tight a ligature. A tight ligature might damage the silicone rubber insulation or sever the vein. Avoid dislodging the lead tip during the stabilizing procedure. Page 35
- **Do not kink leads.** Do not kink, twist, or braid the lead terminal with other leads, as doing so could cause lead insulation abrasion or conductor damage. Page 36
- **Do not bend the lead near the lead-header interface.** Insert the lead terminal straight into the lead port. Do not bend the lead near the lead-header interface. Improper insertion can cause insulation or connector damage. Page 36
- Return all explanted leads to Guidant. Page 37

- **Minimize dissection.** To minimize the possibility of dissection, it is recommended that a guide wire be used when advancing the guiding catheter through the venous system, right atrium, or coronary sinus.
- **Prevent renal failure.** To prevent renal failure associated with the use of contrast media, consider the patient's renal function prior to the implant procedure to determine the type, amount, and rate of injection of the contrast medium while performing a venogram.
- **Implant time.** The VENTAK CHF/CONTAK CD/ EASYTRAK Biventricular Pacing Study data indicate that 80% of implants are completed within 4 hours; 90% are completed within 5 hours. Implants that extend beyond 5 hours are unlikely to have successful completion; the physician should consider terminating the procedure. The implant procedure may be reattempted at a later date, if feasible.

ADVERSE EVENTS

The VENTAK® CHF/CONTAK CD®/EASYTRAK Biventricular Pacing Study (hereafter referred to as the CONTAK CD Study) was a prospective, randomized, controlled, multicenter, double-blind study conducted at 47 sites in the United States and enrolled a total of 581 patients. Of these, 57 patients initially underwent a thoracotomy procedure to receive the Guidant Model 1822 VENTAK CHF AICD; 7 patients underwent a repeat procedure to receive an EASYTRAK lead. An additional 510 patients initially underwent an implant procedure to receive the Model 1823 CONTAK CD CRT-D along with the EASYTRAK (Models 4510/4511/4512/4513) coronary venous, single-electrode pace/sense lead for a total of 517 patients who underwent an EASYTRAK lead implant procedure. In 69 patients the EASYTRAK lead implant attempt was unsuccessful.

Observed Adverse Events

Table 1 provides information on all lead-related and procedure-related adverse events reported from implant through the randomization period in patients attempted or implanted with the EASYTRAK lead. During this period, a total of 765 events were reported in 310 patients. Of these, 155 were classified as complications, and 610 were classified as observations.

Table 1. EASYTRAK Lead-related and Procedure-related Adverse Events Through the Randomization Period

Adverse Event	# of Events (# of pts)[a]	% Complications (Patients)	Complications per 100 Device Months (Events)	% Observations (Patients)	Observations per 100 Device Months (Events)
LV Lead-Related Events					
Loss of capture	43 (41)	5.6 (29)	1.1 (29)	2.5 (13)	0.5 (14)
Inappropriate shock due to oversensing	1 (1)	0.0 (0)	0.0 (0)	0.2 (1)	0.0 (1)
Insulation breach observed	1 (1)	0.2 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Multiple counting[b]	31 (22)	1.0 (5)	0.2 (5)	3.9 (20)	1.0 (26)
Phrenic nerve/diaphragm stimulation	15 (15)	0.4 (2)	0.1 (2)	2.5 (13)	0.5 (13)
Procedure-Related Events					
AV Block	7 (7)	0.0 (0)	0.0 (0)	1.4 (7)	0.3 (7)
Coronary sinus dissection	5 (5)	0.0 (0)	0.0 (0)	1.0 (5)	0.2 (5)
Coronary venous perforation	5 (5)	0.2 (1)	0.0 (1)	0.8 (4)	0.2 (4)
Renal failure	5 (5)	0.2 (1)	0.0 (1)	0.8 (4)	0.2 (4)
Other[c]	18 (18)	1.2 (6)	0.2 (6)	2.3 (12)	0.5 (12)

a. The total number of patients for a given event represents the unique number of patients who experienced that event. The total may not be equal to the sum of patients with complications or observations because some patients experienced more than one event that fell into both categories.

b. Sensing of two ventricular intrinsic events when only one intrinsic event is present due to intraventricular conduction delay.

c. Other procedure related events occurred in three patients or fewer: Guide wire fracture (1), Finishing wire left in lead (1), Pericardial effusion (3), RV lead dislodgement (1), Hypotension due to blood loss (1).

A total of 109 deaths occurred during the study at any point in time. These deaths occurred during the study periods as shown in Table 2 along with the cause of death as adjudicated by an independent events committee.

Table 2. Deaths that Occurred During the Study

All patients enrolled, N=581

		Cause of Death				
Study Period	# of pt deaths	Cardiac: Pump Failure	Cardiac: Arrhythmic	Cardiac: Other	Non-Cardiac	Unknown
After unsuccessful implant procedure	2	1	1	0	0	0
Peri-operative (<= 30 days)	10	5	2	0	2	1
Randomized therapy phase*: No CRT	16	9	0	1	3	3
Randomized therapy phase*: CRT	11	4	1	2	2	2
Post-randomized therapy phase**	70	28	5	1	16	20
Total	109	47	9	4	23	26

* Day 31 to 120 for Phase I patients, day 31 to 210 for Phase II patients
** Day 121 and beyond for Phase I patients, day 211 and beyond for Phase II patients

Potential Adverse Events

Based on the literature and lead implant experience, the following alphabetical list includes possible adverse events associated with implantation of an implantable cardioverter defibrillator lead system:

- Acceleration of arrhythmias
- Air embolism
- Allergic reaction
- Bleeding
- Cardiac tamponade
- Chronic nerve damage
- Conductor coil fracture
- Death
- Elevated thresholds
- Erosion/extrusion
- Extracardiac stimulation (eg, phrenic, diaphragm, chest wall)
- Fibrotic tissue formation (eg, keloid formation)
- Fluid accumulation
- Formation of hematomas or cysts
- Heart block
- Inappropriate therapy (eg, shocks, ATP, pacing)
- Incomplete lead connection with pulse generator
- Infection
- Lead displacement/ dislodgment
- Lead fracture
- Lead insulation breakage or abrasion
- Lead tip deformation and/or breakage
- Local tissue reaction
- Muscle and nerve stimulation
- Myocardial trauma (eg, cardiac perforation, irritability, injury)
- Myopotential sensing
- Oversensing/undersensing
- Pacemaker-mediated tachycardia
- Pericardial rub, effusion
- Pneumothorax
- Random component failures
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Thrombosis/thromboemboli
- Valve damage
- Venous occlusion
- Venous trauma (eg, perforation, dissection, erosion)

In addition to the implantation of an implantable cardioverter defibrillator lead system, possible adverse events associated

with implantation of a coronary venous lead system are listed below in alphabetical order:

- Allergic reaction to contrast media
- Breakage/failure of implant tools
- Coronary venous occlusion
- Coronary venous trauma (eg, perforation, dissection, erosion)
- Prolonged exposure to fluoroscopic radiation
- Renal failure from contrast media used to visualize coronary veins

CLINICAL TRIAL

The following is a summary of findings on the EASYTRAK lead observed during the VENTAK CHF/CONTAK CD/ EASYTRAK Biventricular Pacing Study.

Study Design

The CONTAK CD Study was a prospective randomized, controlled, multicenter, double-blind study conducted at 47 sites in the United States and enrolled a total of 581 patients. All patients enrolled were intended to be implanted with a device capable of delivering both CRT and treating ventricular tachyarrhythmias. Patients were randomized to CRT Off (VVI lower rate 40) or CRT On (VDD). The study began as a crossover design (called "Phase I") and enrolled 248 patients with a primary endpoint of functional status with three months of follow-up. The study was later modified to a parallel design (called "Phase II") and enrolled 333 patients with a longer, six-month follow-up. The data from the first three months of the crossover phase were pooled with data from the six-month parallel phase. The visit schedule and testing requirements remained the same. Additionally, while the study originally used the VENTAK CHF AICD in conjunction with epicardial leads placed via thoracotomy, the CONTAK CD CRT-D and EASYTRAK lead (placed transvenously) were added to the protocol later in the study.

Inclusion/Exclusion Criteria

Patients enrolled in the study were required to meet the following inclusion criteria:

- Meet the general indication for ICD implant
- Symptomatic heart failure despite optimal drug therapy (ACE inhibitors with diuretic and/or digoxin, as determined to be indicated and tolerated by the patient's physician-investigator)
- Left ventricular ejection fraction ≤35%
- QRS duration ≥ 120 ms
- Age ≥ 18 years
- Normal sinus node function

Patients were excluded from the investigation if they met any of the following criteria:

- Meet the general indications for permanent antibradycardia pacing, including pacemaker dependence
- Have chronic, medically refractory atrial tachyarrhythmias
- Require concomitant cardiac surgery
- Are unable to undergo device implant, including general anesthesia if required
- Are unable to comply with the protocol and follow-up requirements, including exercise testing
- Have a life expectancy of less than six months due to other medical conditions
- Have amyloid disease (amyloidosis)
- Have hypertrophic obstructive cardiomyopathy
- Require in-hospital continuous intravenous inotropes
- Have pre-existing cardioversion/defibrillation leads other than those specified in the investigational plan (unless the investigator intends to replace them with permitted cardioversion/defibrillation leads)
- Women who are pregnant or not using medically accepted birth control
- Have a mechanical tricuspid prosthesis
- Involved in other cardiovascular clinical investigations of active therapy or treatment

Follow-Up Schedule

Pre-implant visit:	Initial assessment of patient eligibility; taking of patient history.
Implant:	Implant of investigational devices and acute device testing. Randomization status (CRT or No CRT) was assigned for implementation after a 30-day Recovery Period.
Recovery Period:	Minimum 30-day period over which the patient recovered from the implant procedure and had his/her heart failure medications adjusted, but with no CRT regardless of the randomization assignment.
Post-Recovery Visit:	First visit after the Recovery Period in which patients underwent Special Testing[a] to establish their baseline condition, after which the randomization assignment was implemented (CRT or No CRT).
Three- and six-month Visits:	Evaluation of randomized therapy with Special Testing[a] and device function at three- and six-months after the Post-Recovery Visit.
Quarterly Visits:	After the six-month visit, patients were seen for routine evaluation of device function and patient condition.

a. Special Testing included a Symptom-Limited Treadmill Test with measurement of oxygen uptake (Peak VO2), a Six-Minute Walk, Echocardiography, Holter monitoring, blood chemistry testing, and a Quality of Life (QOL) questionnaire.

Patient Groups

The CONTAK CD Study included patients with symptomatic heart failure despite optimal drug therapy. This population included patients who were NYHA Class II/III/IV at the time of implant.

Based upon the clinical results from the covariate analyses in this study, and the internal consistency of these clinical findings with those from other completed CRT studies, the patient subgroup with NYHA Class III/IV heart failure in this study was examined further.

Results indicate that patients with NYHA Class III/IV heart failure demonstrated the greatest improvement. Therefore, the CONTAK CD system indications for this PMA are for patients with NYHA Class III/IV heart failure.

- **All Patients: All patients (NYHA Class II/III/IV at the time of implant)** implanted with an investigational system (N = 501). Ten patients died and one withdrew before the Post-Recovery Visit. Therefore, therapy effectiveness analyses used N = 490.
- **NYHA Class III/IV (Advanced Heart Failure):** This subgroup was defined as those patients with moderate to severe heart failure at the time of the Post-Recovery Visit (N = 227). A percentage of patients either had an improvement or worsening of their NYHA Class during the post-implant recovery period. The patients in the Advanced Heart Failure subgroup were only those who remained in NYHA Class III/IV at the end of the post recovery period. This subgroup was determined from interaction analysis of pre-selected covariates with the functional status endpoints.

Lead Endpoints

Lead and System Effectiveness:

Lead: Left ventricular pacing thresholds, biventricular sensing, biventricular lead impedance, and lead placement success rate.

System: VF detection time, biventricular antitachycardia pacing (ATP) efficacy.

Lead and System Safety:

Lead: Incidence of lead-related adverse events.

System: Incidence of severe, device-related adverse events and operative mortality.

Implant Data

There were 517 patients enrolled in the CONTAK CD Study who underwent an implant procedure for an EASYTRAK coronary venous single-electrode pace/sense lead.

Clinical Investigation

The lead study was a nonrandomized study comparing the performance of the EASYTRAK lead to criteria established prospectively. The objective of this investigation was to demonstrate the safety and effectiveness of the EASYTRAK lead. The EASYTRAK lead was successfully implanted in 448/517 (86.7%) of patients in whom an EASYTRAK lead implant was attempted. The mean implant duration of the study in the 448 patients who received the EASYTRAK lead was 17.7 months (range: 0 to 29.5 months) with a cumulative implant duration of 623 patient-years. Demographic information on all 517 patients studied is shown in Table 3.

Table 3. Demographic information on all Patients (N = 517)

Characteristic	Patients	%
Gender		
Male	436	84
Female	81	16
Age at Implant (years)	66 ± 11	
Mean LVEF	21 ± 6	
Etiology of Cardiomyopathy		
Ischemic	355	69
Non-ischemic	162	31
NYHA Classification		
II	177	34
III	296	58
IV	44	9

The EASYTRAK lead pacing threshold was measured with a CONTAK CD device at 0.5 ms pulse width. The EASYTRAK R-wave amplitudes and lead impedance were also measured with the CONTAK CD device in a biventricular lead configuration (from the EASYTRAK lead and right ventricular lead connected in parallel).

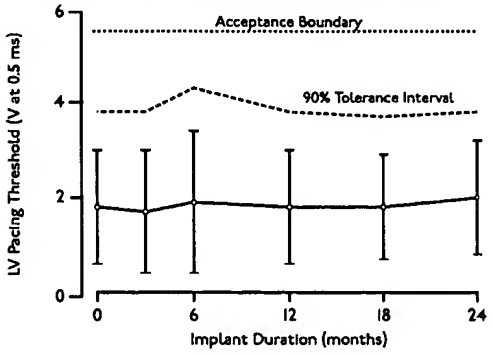
The mean chronic (> 12 months) pacing threshold (0.5 ms pulse width) of the EASYTRAK lead was 1.8 ± 1.2 V, mean

chronic biventricular R-wave amplitude was 9.8 ± 4.4 mV, and mean chronic biventricular lead impedance was 351 ± 51 Ω.

Lead Effectiveness

The effectiveness of the EASYTRAK lead was determined with chronic left ventricular pacing thresholds, chronic biventricular sensed R-wave amplitudes, and chronic biventricular lead pacing impedances.

All patients implanted with an EASYTRAK lead at first implant, N = 443

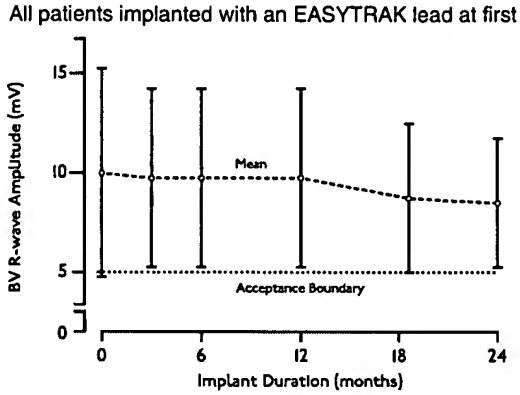


Statistic	Implant	3 Months	6 Months	12 Months	18 Months	24 Months
N	435	347	330	233	103	25
Mean +/- SD	1.8 +/- 1.2	1.7 +/- 1.3	1.9 +/- 1.5	1.8 +/- 1.2	1.8 +/- 1.1	2.0 +/- 1.2
Range	0.2 - 7.5	0.2 - 7.5	0.2 - 7.5	0.4 - 7.5	0.6 - 7.5	0.6 - 5.0
Upper Tolerance Limit	3.8	3.8	4.3	3.8	3.7	3.9

* EASYTRAK lead models: 4511, 4512, and 4513

Figure 1. Threshold measurements.

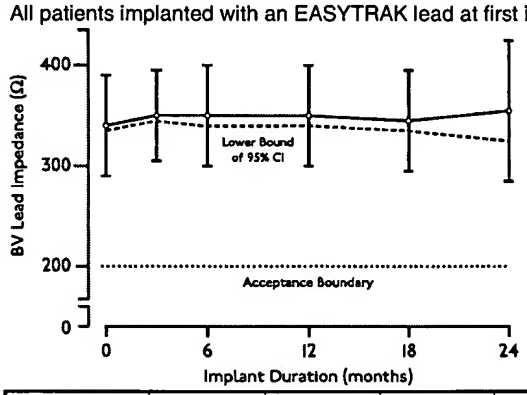
It was hypothesized that the upper tolerance limit of the chronic left ventricular pacing threshold of the EASYTRAK lead be less than 5.5 V to ensure that an adequate safety margin exists. Chronic left ventricular pacing thresholds are within this limit.



Statistic	Implant	3 Months	6 Months	12 Months	18 Months	24 Months
N	433	346	326	220	99	23
Mean +/- SD	10.0 +/- 5.2	9.9 +/- 4.4	9.9 +/- 4.5	9.8 +/- 4.4	8.9 +/- 3.5	8.5 +/- 3.3
Range	1.9 - 25.0	1.4 - 25.0	1.7 - 25.0	1.2 - 25.0	2.6 - 20.4	2.2 - 13.6

Figure 2. Biventricular sensed R-wave amplitude.

Mean chronic biventricular R-wave amplitudes are measured as a combination of the R-waves from both the right ventricle (commercially available ENDOTAK lead) and left ventricle (EASYTRAK lead). It was hypothesized that the mean biventricular R-wave amplitude be greater than 5 mV to ensure proper sensing. The performance of the EASYTRAK lead system was significantly above this value ($p < 0.01$).



Statistic	Implant	3 Months	6 Months	12 Months	18 Months	24 Months
N	436	355	336	237	107	26
Mean +/- SD	340 +/- 46	352 +/- 47	349 +/- 50	351 +/- 51	347 +/- 46	356 +/- 67
Range	243 - 550	248 - 519	186 - 534	237 - 513	254 - 507	267 - 520
95% CI	(336, 344)	(347, 357)	(344, 355)	(345, 358)	(338, 356)	(329, 383)

Figure 3. Biventricular pacing impedance.

The impedance measured by the CONTAK CD device is the parallel combination of the left ventricular (EASYTRAK) and right ventricular (ENDOTAK) leads simultaneously. Therefore, the biventricular lead impedance will be substantially less than that of either lead alone. The average measured biventricular R-wave amplitude is between 8 to 10 mV with the normal range typically between 5 and 20 mV. The average measured biventricular impedance is 350 Ω with the range typically between 250 and 500 ohms. It was hypothesized that the lower limit of the 95% confidence interval of the mean chronic biventricular lead impedance would be greater than 200 Ω to ensure proper pulse generator function. The lower limit of the 95% confidence interval of the chronic biventricular lead impedance exceeds this value (Figure 3).

Lead Placement Success Rate

The EASYTRAK lead was implanted in 448/517 (87%) of patients who underwent the implant procedure. Table 4 shows the reasons for inability to place the EASYTRAK lead. Table 5 provides the EASYTRAK lead implant success rate.

Table 4. Reasons for Unsuccessful EASYTRAK Lead Implant

Patients with unsuccessful attempt to implant EASYTRAK lead (N=69)

Reason	# of pts	%
Inability to locate or cannulate the coronary sinus	29	42.0
Dislodgment of EASYTRAK lead while removing guide catheter	13	18.8
Inability to advance the lead to a stable position	11	15.9
Inability to obtain adequate pacing thresholds	6	8.7
Procedure stopped due to coronary sinus dissection or perforation	5	7.2
Procedure stopped due to transient AV block	1	1.4
Procedure stopped due to venous perforation during subclavian stick	1	1.4
Reason not stated	1	1.4
Extracardiac stimulation	1	1.4
Inability to place an atrial pace/sense lead	1	1.4
Total	69	100%

Table 5. EASYTRAK Lead Placement Success Rate

All patients implanted or attempted with EASYTRAK lead, N=517

Measurement	All Procedures
Number of patients implanted or attempted	517
Number of placements* of the EASYTRAK Lead	448
Rate	87%
95% CI	(84%, 90%)

*Defined an EASYTRAK implant procedure that is concluded with the implant of the investigational cardiac resynchronization system.

Although some situations such as patient anatomy and poor thresholds cannot be avoided, increased investigator experience with the EASYTRAK lead and accessories was associated with improved success, decreased total procedure time (measured skin-to-skin), and decreased fluoroscopy exposure time (Figure 4).

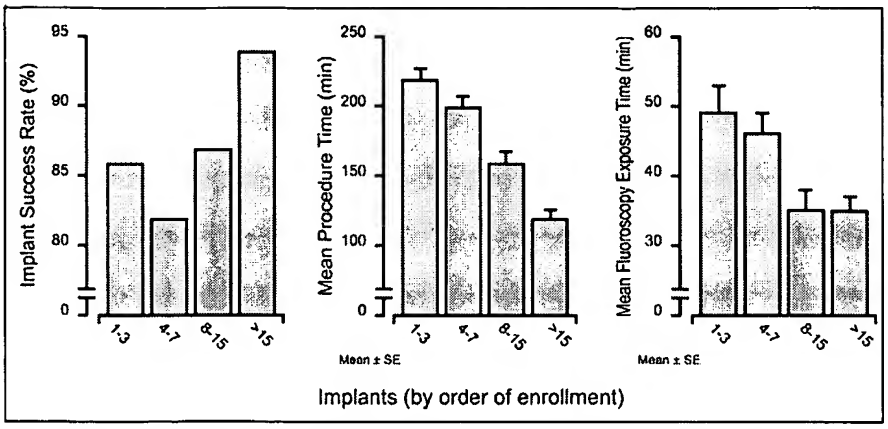


Figure 4. EASYTRAK Lead Success Rate, Procedure Time, Fluoroscopy Exposure Time.

Lead Safety

Safety was established using the rate of adverse events that are either related to the EASYTRAK lead or to the implant procedure necessary to place the EASYTRAK lead.

An EASYTRAK lead implant procedure was performed in 517 patients with 448 patients (86.7%) being successfully implanted with the EASYTRAK lead. The upper boundary of the 95% confidence interval was hypothesized to be less than 23% at six months (Table 6).

Table 6. Lead Related Adverse Events at Six Months

Patient Population	n	Event Rate (%)	95% Confidence Interval
All Patients	517	12.2	(9.4, 15.0)
NYHA Class III/IV	201	17.4	(12.7, 22.7)

Fifty-three lead-related adverse events were reported during the clinical investigation of the EASYTRAK coronary venous single-electrode pace/sense lead among the 448 patients who were implanted with an EASYTRAK lead. Twenty-seven procedure-related adverse events were reported among the 517 patients who underwent the implant procedure for an EASYTRAK lead. The overall lead-related adverse event rate was 14.5% [95% CI (11.5–17.5%)].

The most common of the 53 lead-related adverse events (> 1% incidence) included loss of left ventricular capture (31 patients, 6.9%), ventricular oversensing (11 patients, 2.5%), and extracardiac stimulation (9 patients, 2.0%). These events were typically resolved with surgical intervention.

The most common of the 27 procedure-related adverse events (> 1% incidence) included coronary venous trauma (10 patients, 2.0%), transient atrioventricular block (6 patients, 1.2%), and transient renal failure (5 patients, 1.0%). These events were typically resolved without intervention and no permanent long-term sequelae were reported.

Warranty

See the enclosed Lead Information card for warranty. For additional copies, please contact Guidant Corporation at the address on the back cover.

Refer to the Contraindications, Warnings, Precautions, and Adverse Events sections of this manual for information concerning the performance of this device.

DEVICE FEATURES

Detailed Device Description

Features of the EASYTRAK lead include the following:

- **Over-The-Wire Lead Design:** The lead design consists of an open-lumen conductor coil that tracks over a 0.014-in (0.36-mm) diameter guide wire.
- **Steroid:** The distal end contains a nominal dose of 0.7 mg dexamethasone acetate contained in a silicone rubber collar. Upon exposure to body fluids, the steroid elutes from the lead to help reduce tissue inflammation response at implant.
- **Slotted-Ring Single Electrode:** The slotted-ring electrode provides a pacing and sensing surface by providing tissue contact in the coronary venous system.

- **Pace/Sense Configurations:** The EASYTRAK lead offers various pace/sense configurations depending upon the programming options of a Guidant compatible CRT device.
- **Distal Tip:** The distal tip is protected by molded silicone rubber. This protection allows for lead advancement through the coronary venous system.
- **Tined Electrode Fixation:** Two silicone tines, located proximal to the pace/sense electrode, provide passive fixation of the lead after surgical placement.
- **Lead Body:** The distal portion of the lead body is 4.8 F in diameter and consists of a trifilar coil that provides a conductive pathway. The conductor is sheathed in silicone insulation. In addition, the silicone rubber is covered with a polyurethane protective sleeve.
- **LV-1 Connector:** The LV-1 connector is 6 F in diameter. This allows the guiding catheter to be removed over the connector after lead placement.

LEAD EVALUATION

Implant Information

Proper surgical procedures and techniques are the responsibility of the medical professional. The described implant procedures are furnished for informational purposes only. Each physician must apply the information in these instructions according to professional medical training and experience.

The EASYTRAK lead is not designed, sold, or intended for use except as indicated.

Items Included

Items packaged include the following:

- (1) EASYTRAK Lead
- (1) FINISHING WIRE® Universal
- (2) Suture Sleeves
- (1) Wire Guide
- (1) Vein Pick
- Literature Packet

WARNING: Instructions in the lead manual should be used in conjunction with other resource material including the applicable Guidant CRT device physician's manual and instructions for use on any implant accessories.

Additional Implant Tools

The following is a list of interventional devices used for implanting the lead; but not packaged with the lead:

- Guiding catheter, 8 F or larger, minimum 0.087-in (2.2-mm) inside diameter, that is intended for accessing the coronary venous system
    - Guide wire, 0.032–0.038-in (0.81–0.97-mm) diameter (optional), that is intended for use in the coronary venous vasculature
    - Deflectable tip mapping catheter, 6 F (optional), that is intended for use in the coronary sinus ostium
- Standard occlusion balloon, 6 F, that is intended for use in obtaining venograms by occluding the coronary sinus
- Guide wire, 0.014-in (0.36-mm) diameter, that is intended for use in the coronary venous system and torque device
- Implant accessories

Opening Instructions

The outer package and sterile tray should be opened under clean conditions. To ensure sterility, the sealed inner sterile tray must be opened using accepted aseptic technique by scrubbed, masked personnel. The sterile tray is opened by peeling back the cover.

Sterilization

CAUTION: Guidant sterilizes the lead and accessories with ethylene oxide gas (EtO) before final packaging. When they are received, they are sterile and ready for use. If the container is wet, damaged, punctured, or if the seal is broken, return the lead to the nearest Guidant representative. Never attempt to resterilize the lead or accessories. Instead, return the lead to Guidant at the address on the back cover of this manual.

Storage

Recommended storage temperature range is 20°C to 25°C. Avoid temperatures above 50°C.

Surgical Preparation

Instrumentation for heart monitoring, imaging (fluoroscopy), external defibrillation, and pacing threshold and sensitivity measurements should be available during implantation. The sterile field should be large enough to accommodate the use of the guide wires. Sterile duplicates of all implantable items should also be available for use if accidental damage or contamination occurs. Always isolate the patient from potentially hazardous leakage current when using electrical instrumentation.

Nominal lengths of the leads are as follows:

Model	4510	4511	4512	4513
Length	65 cm	72 cm	80 cm	90 cm

Selection of the lead length appropriate to the patient's cardiac anatomy is a matter of medical judgment.

Lead Accessories

The following items are packaged in the lead tray and are also available from Guidant as accessory items:

Vein Pick

The vein pick is a sterile, disposable, nontoxic, nonpyrogenic, plastic device designed to assist placement of the guiding catheter into the vein.

To use the vein pick during a cutdown procedure, isolate and open the selected vein using an appropriate instrument. Introduce the point of the vein pick via this incision into the lumen of the vein. With the point of the vein pick facing in the direction of the desired guiding catheter passage, gently raise and tilt the pick. Pass the guiding catheter under the vein pick and into the vein.

CAUTION: The vein pick is not intended either for puncturing the vein or for dissecting tissue during a cutdown procedure.

FINISHING WIRE Universal

The FINISHING WIRE Universal is designed to stabilize the positioned lead in the coronary venous system during guiding catheter removal.

WARNING: If using a finishing wire accessory kit, use the corresponding finishing wire model for the lead length (Table 7). If the wrong length finishing wire is used, the finishing wire tip may extend out the distal end of the lead or not stabilize the lead properly.

Table 7. Lead Model and Length and Corresponding FINISHING WIRE Universal Model

Lead Model & Length	Finishing Wire Model
4510, 65 cm	6002
4511, 72 cm	6003
4512, 80 cm	6004
4513, 90 cm	6005

CAUTION: The finishing wire MUST BE REMOVED before connecting the lead to the pulse generator.

Wire Guide

The wire guide is intended to ease insertion of a guide wire into the open lumen at the terminal of the lead.

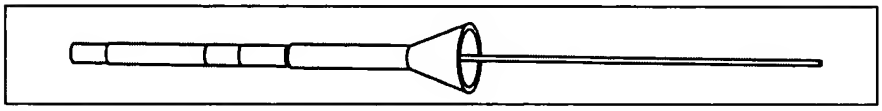


Figure 5. Using the wire guide.

Suture Sleeve (Attachable)

The attachable suture sleeve is an adjustable, tubular reinforcement positioned over the outer lead insulation. It is designed to secure and protect the lead at the venous entry site after lead placement. Using a suture sleeve reduces the possibility of structural damage caused by suturing directly over the lead body.

CAUTION: Do not suture directly over the lead body, as this may cause structural damage. Use the suture sleeve to secure the lead at the venous entry site.

Handling the Lead

Observe the following when handling the lead:

WARNING: The lead is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, or lead dislodgment.

CAUTIONS:

- Do not wipe or immerse the distal lead tip in fluid prior to implant. Such treatment will reduce the amount of steroid available when the lead is implanted.
- Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted.
- The conductor insulation is silicone rubber, which can attract particulate matter, and therefore must always be protected from surface contamination.

IMPLANTATION

Inserting the Lead

The lead may be inserted using one of the following two methods:

Via cutdown through the left or right cephalic vein.

Only one incision over the deltopectoral groove is required to insert the guiding catheter through the cephalic vein. The endocardial lead is inserted into the right or left cephalic vein in the deltopectoral groove.

The vein pick packaged with this lead can be used during a cutdown procedure to aid insertion of the guiding catheter into the vein. Before inserting the guiding catheter, see the section, "*Lead Accessories*" for instructions on using the vein pick.

Percutaneously or via cutdown through the subclavian vein or internal jugular vein—typically the left subclavian or right internal jugular vein.

A subclavian introducer set is available from Guidant for use during percutaneous lead insertion.

CAUTION: When attempting to implant the lead via a subclavian puncture, do not insert the lead under the medial one-third region of the clavicle. Damage or chronic dislodgment to the lead is possible if the lead is implanted in this manner. If implantation via the subclavian vein is desired, the lead must enter the subclavian vein near the lateral border of the first rib and must avoid penetrating the subclavius muscle. It is important to observe these implant precautions to avoid clavicle/first rib damage or chronic dislodgment to the lead. It has been established in the literature that lead fracture can be caused by lead entrapment in such soft tissue structures as the subclavius muscle, costocoracoid ligament, or the costoclavicular ligament.[2]

Leads placed by percutaneous subclavian venipuncture should enter the subclavian vein, where it passes over the first

rib (rather than more medially), to avoid entrapment by the subclavius muscle or ligamentous structures associated with the narrow costoclavicular region.[3] Guidant recommends introducing the lead into the subclavian vein near the lateral border of the first rib.

The syringe should be positioned directly above and parallel to the axillary vein to reduce the chance that the needle will contact the axillary or subclavian arteries or the brachial plexus. Use of fluoroscopy is helpful in locating the first rib and in guiding the needle. The steps below explain how to identify the skin entry point and define the course of the needle toward the subclavian vein where it crosses the first rib.

1. Referring to Figure 6, identify points St (sternal angle) and Cp (coracoid process).

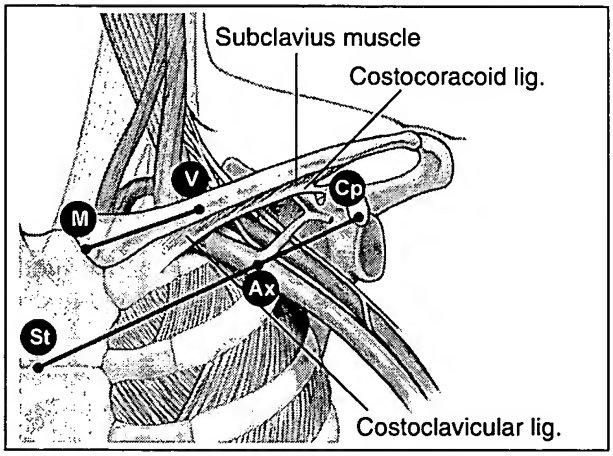


Figure 6. Landmarks identify the entry point for a percutaneous subclavian venipuncture.

2. Visually draw a line between St and Cp, and divide the segment into thirds. The needle should pierce the skin at the junction of the middle and lateral thirds, directly above the axillary vein (point Ax).

3. Place an index finger on the clavicle at the junction of the medial and middle thirds (point V), beneath which point the subclavian vein should be located.

4. Press a thumb against the index finger and project one or two centimeters below the clavicle to shield the subclavius muscle from the needle (when hypertrophy of the

pectoralis muscle is apparent, the thumb should project about two centimeters below the clavicle because the subclavius muscle should be hypertrophied as well) (Figure 7).

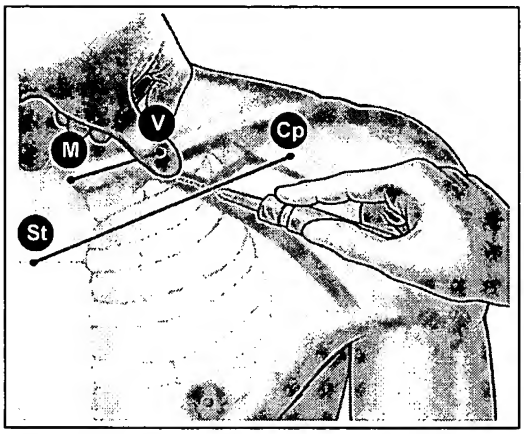


Figure 7. Location of thumb and needle entry.

5. Feel with the thumb the pressure from the passage of the needle through the superficial fascia; direct the needle deep into the tissues toward the subclavian vein and the underlying first rib. Fluoroscopic guidance will reduce the chance that the needle would pass below the first rib and into the lung.

CAUTION: When implanting the lead via a subclavian puncture, allow slack in the lead between the suture sleeve and the venous entry site. This will help minimize flexing at the suture sleeve and interaction with the clavicle/first rib region.

Positioning the Lead

Positioning the lead includes the following steps:

1. ***Insert a guiding catheter*** into the ostium of the coronary sinus to provide a path for lead placement.
2. ***Obtain a venogram*** to visualize the coronary venous system.
3. ***Place the lead*** through the guiding catheter in the coronary venous system by advancing the lead over a guide wire.

Referring to Figure 8, the lead is introduced into the coronary venous system through the ostium of the coronary sinus and advanced into its tributaries. The coronary sinus and its tributaries include the great cardiac vein, middle cardiac vein, left posterior vein, and left marginal vein. All cardiac veins are potential sites for implantation of the EASYTRAK lead. Variability in patient anatomy may preclude placement in one or more of the suggested sites.

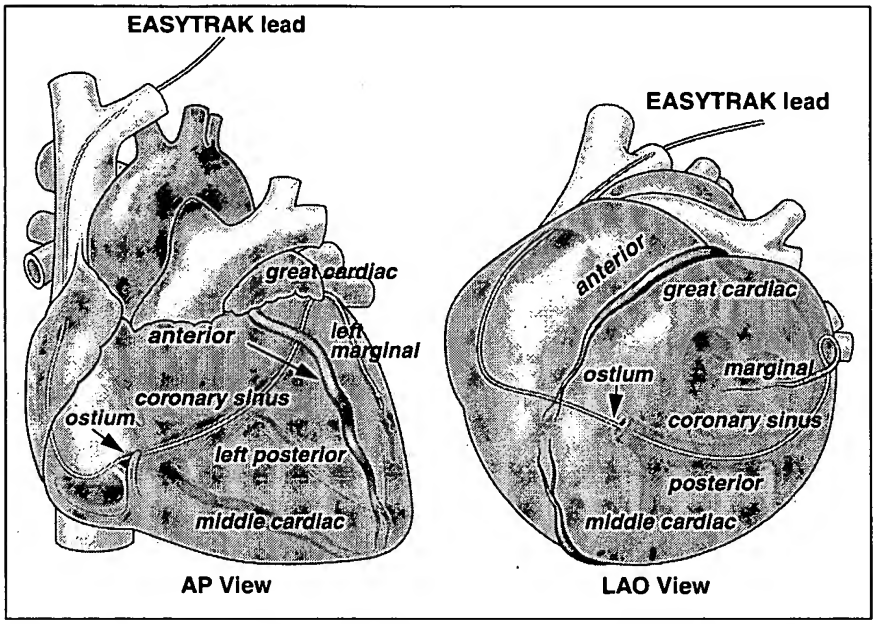


Figure 8. Anterior Posterior (AP) and Lateral Anterior Oblique (LAO) View of the Coronary Venous System.

Note: *It is recommended that a venogram be performed to determine the patient's cardiac anatomy. Any preexisting condition of the patient, eg, coronary stent or coronary artery bypass graft (CABG), should be taken into consideration while using proper medical judgement to determine the best lead implant site.*

Inserting the Guiding Catheter

Recommended methods for finding the coronary ostium include but are not limited to the following: **a)** placing a guide wire 0.032–0.038-in (0.81–0.97-mm) diameter in the ostium first and then following the guide wire with the guiding catheter or **b)** inserting a 6 F (or smaller) fixed curve or deflectable tip mapping catheter through the guiding catheter and then into the ostium.

Notes:

- *Prior to inserting the lead into the guiding catheter, the inner tool must be removed.*
- *It is recommended that the guiding catheter be placed first, prior to the introduction of any leads into the heart. This will help prevent possible lead dislodgments caused by locating the ostium of the coronary sinus with the guiding catheter.*

Obtaining a Venogram

CAUTION: Risks associated with this procedure are similar to any other catheterization procedure in the coronary sinus. Some patients can have a physical intolerance to different types of contrast agents. If this is known in advance, the physician should select an appropriate agent.

Once the guiding catheter is in place and while under fluoroscopy, inject a small amount of contrast medium into the coronary sinus to confirm proper placement of the guiding catheter tip in the coronary sinus. The contrast agent will flow out of the coronary sinus.

Once the position is confirmed, use a minimum amount of contrast to identify the coronary sinus branch vein. Save the acquired venogram for future reference of the venous anatomy.

CAUTIONS:

- At the physician's discretion an occlusion balloon catheter may be used. Inflate the balloon to the recommended volume. Inject the contrast medium through the injection port to opacify the sinus and the distal venous branches. Immediately deflate the balloon after the venogram is obtained.

- The type, amount, and rate of injection of the contrast medium must be determined by the physician's medical judgment regarding the adequacy of the venogram obtained.

Placing the Lead

The following section describes two preferred methods for the EASYTRAK lead placement after the guiding catheter has been positioned in the coronary sinus and a venogram has been obtained.

Notes:

- *The guiding catheter helps to advance the lead into the venous system and can help protect the EASYTRAK lead during the placement of other leads.*
- *To prevent blood from clotting in the lead, Guidant recommends flushing the inner lumen of the lead and the guide wire's protective hoop with heparinized saline* ***before and during*** *guide wire use.*

Method A

1. Insert the 0.014-in (0.36-mm) diameter guide wire into the guiding catheter and advance the tip of the wire through the coronary sinus to the desired position within the venous system.
2. Insert the proximal end of the guide wire into the distal opening of the lead. While holding the guide wire in place, advance the lead over the wire to the desired lead position.

Method B

1. Insert the 0.014-in (0.36-mm) diameter guide wire into the lead. Extend less than 2 cm of the guide wire beyond the distal tip of the lead to ensure the guide wire slides easily through the lumen. Retract the guide wire fully into the lead tip prior to introduction into the guiding catheter.
2. Insert the lead/guide wire assembly into the guiding catheter. Under fluoroscopy, verify the tip of the lead has emerged from the guiding catheter. Advance the guide

wire through the coronary sinus to the desired position within the venous system.

3. While holding the guide wire in place, advance the lead over the wire to the desired lead position.

CAUTIONS:

- Use fluoroscopy to verify the guide wire does not prolapse and catch on the distal tip of the lead. If this occurs, slowly extend the wire beyond the distal tip to free the guide wire and then retract it to reestablish movement of the guide wire.
- If the guide wire cannot be retracted, withdraw the lead/guide wire assembly through the guiding catheter. Remove the guide wire through the distal tip of the lead and reintroduce the lead using a new guide wire. Follow the positioning procedures previously discussed.
- Flushing a clotted lead can compromise lead integrity. If clotting is suspected, remove the lead from the body and soak the lead in heparinized saline. Insert a guide wire into the distal tip of the lead and advance the wire proximally through the terminal to clear clotting. If unsuccessful, use a new lead.
- Applying tools to the distal end of the lead may result in lead damage.

Evaluating Lead Position

Verify electrical performance of the lead using a pacing system analyzer or similar monitor before attaching the lead to the pulse generator. Threshold measurements can be taken immediately after the lead is positioned.

Once the lead is placed in the desired location, partially withdraw the guide wire tip into the pacing lead so it does not extend beyond the lead tip. Perform the following measurements. If the results are unsatisfactory, lead system repositioning or replacement may be required.

Perform the following measurements:

- Voltage threshold at 0.5 ms pulse width
- R-wave amplitude
- Pacing impedance

Table 8. Recommended Threshold and Sensing Measurements

Ventricular Data	
Voltage threshold[a]	≤3.0 V
R-wave amplitude	≥ 5.0 mV
Lead Impedance	300-1200 Ω

a. Pulse width setting 0.5 ms.

Repositioning the Lead

If the measurements do not conform to these values, fully reinsert the guide wire and reposition the lead using the positioning procedures previously discussed. Verify that measurements are appropriate.

Removing the Guiding Catheter

Once the lead is positioned, remove the guide wire from the lead. Next, grasp the FINISHING WIRE Universal and pull the proximal end from the outer protective ring. Unclip the wire from the retainer. Push the wire into the ring so the distal end exits the retainer, underneath the outer ring. Using short strokes, carefully insert the distal end of the finishing wire into the lead. Advance the finishing wire until the finishing wire cap engages the terminal pin of the lead.

Peel away the introducer sheath, if used. While holding the lead and finishing wire in place, use short, gentle strokes to remove the guiding catheter. Hold the proximal end of the lead near the venous entry site, disconnect the finishing wire from the terminal pin and withdraw the finishing wire from the lead. Verify under fluoroscopy that the lead has not moved.

Next, hold the proximal end of the lead near the venous entry site and withdraw the finishing wire. Allow extra slack in the lead in the atrium for a strain relief to reduce the chance of dislodgment.

CAUTIONS:

- Do not bend the finishing wire in the lead. Bending the finishing wire could lock it in the lead or damage the conductor coil.
- If the finishing wire cannot be retracted from the lead, withdraw the lead and finishing wire together. Do not implant with the finishing wire inside the lead.

Securing the Lead

After the lead is satisfactorily positioned, use the following steps to secure the lead to the vein to achieve permanent hemostasis and lead stabilization. Suture sleeve tie-down techniques can vary with the lead insertion technique used. An attachable suture sleeve is provided for this purpose.

Percutaneous Implant Technique

1. Place the suture sleeve over the lead body. Slide the suture sleeve deep into the tissue (Figure 9).
2. Using both grooves, ligate the suture sleeve to the lead.
3. Next, secure the sleeve and lead to the fascia.

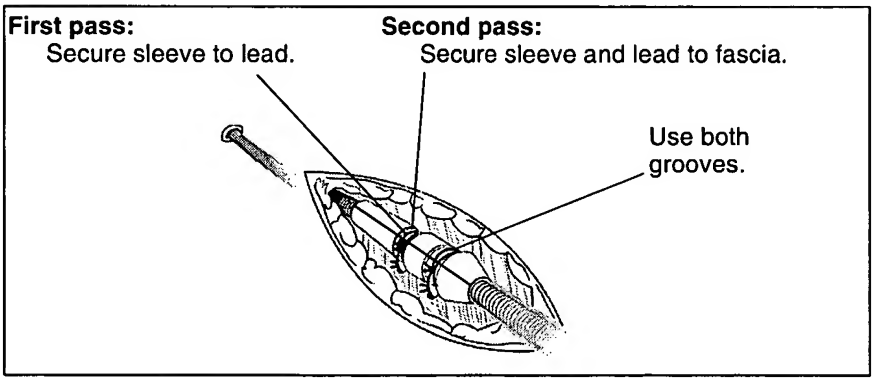


Figure 9. Using the sleeve with the percutaneous implant technique.

4. Check the suture sleeve after tie-down to demonstrate stability and lack of slippage by grasping the suture sleeve with fingers and trying to move the lead in either direction.

Venous Cut-Down Technique

1. Place the suture sleeve over the lead body. Slide the suture sleeve into the vein past the distal pre-formed groove. Ligate the vein around the suture sleeve to obtain hemostasis. Next, using the same groove, secure the lead and vein to the adjacent fascia (Figure 10).

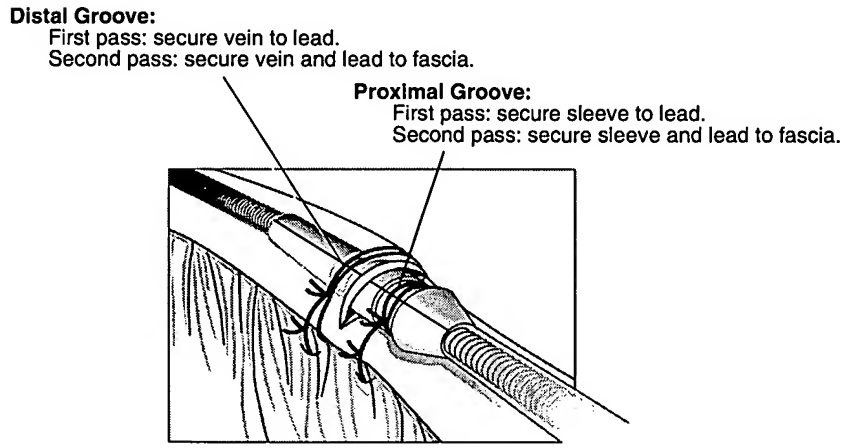


Figure 10. Using the sleeve with the venous cutdown technique.

2. Using the proximal pre-formed groove, secure the sleeve to the lead. Using the same groove, secure the sleeve and lead to the adjacent fascia.

3. Check the suture sleeve after tie-down to demonstrate stability and lack of slippage by grasping the suture sleeve with fingers and trying to move the lead in either direction.

Note: *If venous entry is made using a Guidant lead introducer, ligate the lead to the adjacent fascia using the suture sleeve to prevent lead movement.*

CAUTION: When ligating the vein, avoid too tight a ligature. A tight ligature might damage the silicone rubber insulation or sever the vein. Avoid dislodging the lead tip during the stabilizing procedure.

Connection to a Pulse Generator

Remove the finishing wire from the lead before connecting the lead to the pulse generator. A finishing wire left in the lead could cause (1) lead perforation or (2) myocardial or coronary venous perforation.

When the lead is secured at the venous entry site, reverify position and threshold measurements and then connect the lead to the pulse generator using the procedure described in the applicable pulse generator physician's manual.

CAUTIONS:

- Do not kink, twist, or braid the lead terminal with other leads, as doing so could cause lead insulation abrasion or conductor damage.
- Insert the lead terminal straight into the lead port. Do not bend the lead near the lead-header interface. Improper insertion can cause insulation or connector damage.

Notes:

- *Guidant suggests using sterile water if a lubricant is needed when connecting the lead to the pulse generator.*
- *If the lead terminal pin will not be connected to a pulse generator at the time of lead implantation, the lead connector must be capped before closing the pocket incision. The LV-1 lead cap is designed specifically for this purpose. Place a suture around the lead cap to keep it in place.*

Giving consideration to patient anatomy and pulse generator size and motion, gently coil any excess lead and place adjacent to the pulse generator. It is important to place the lead into the pocket in a manner that minimizes lead tension, twisting, sharp angles, and/or pressure.

Returning Explanted Products

Return all explanted leads to Guidant. Examination of explanted leads can provide information for continued improvement in system reliability. Use a Guidant Returned Product Kit to properly package the lead and complete an Observation/Complication/Out-of-Service Report form. Send the form and kit to Guidant at the address on the back of this manual.

CAUTION: Return all explanted leads to Guidant.

Note: *Disposal of explanted devices is subject to local, state, and federal regulations. Contact your Guidant representative or call Guidant at the telephone number on the back of the manual for a Returned Product Kit.*

REFERENCES

1. LV-1 refers to the Guidant LV® proprietary connector.
2. Magney JE, et al. Anatomical mechanisms explaining damage to pacemaker leads, defibrillator leads, and failure of central venous catheters adjacent to the sternoclavicular joint. PACE. 1993;16:445-457.
3. Magney JE, et al. A new approach to percutaneous subclavian venipuncture to avoid lead fracture or central venous catheter occlusion. PACE. 1993;16:2133-2142.

SPECIFICATIONS (NOMINAL)

Model	4510/4511/4512/4513
Length	4510 - 65 cm 4511 - 72 cm 4512 - 80 cm 4513 - 90 cm
Terminal compatibility	(1) LV-1
Electrode configuration	Single
Compatibility	Pulse generators that accept LV-1 connectors
Recommended introducer size[a]	8 F or larger
Steroid	0.7 mg dexamethasone acetate
Conductors:	
Conductor type	Trifilar coil
Conductor material	Platinum clad tantalum
Electrode:	
Electrode surface area	3.5 mm^2
Electrode material	Platinum iridium
Lead Body:	
Lead body (distal) diameter	1.58 mm (4.8 F)
Lead body insulation material	Silicone rubber
Lead body protective sleeve material	Polyurethane
Tines:	
Number of tines	2
Angle of tine projection	45 degrees
Angle of tine separation	180 degrees
Tine material	Silicone rubber

a. Introducer size is determined by guiding catheter size.

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Medtronic
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News Release

Medtronic Announces FDA Approval, U.S. Release Of Attain™ OTW Left-Heart Lead For Heart Failure Patients

Over-the-wire, steroid-eluting lead joins industry-leading family of products designed for cardiac resynchronization therapy procedures

MINNEAPOLIS, May 3, 2002 – Medtronic, Inc. (NYSE: MDT), today announced approval by the U.S. Food and Drug Administration (FDA) of the Attain™ OTW (over-the-wire) Model 4193 left-heart lead for delivery of cardiac resynchronization therapy for moderate to severe heart failure.

The Attain OTW lead is the latest in the company's industry-leading family of leads for cardiac resynchronization therapy. Specially designed to provide easier left-heart access, it gives physicians an additional tool to meet the key challenge in cardiac resynchronization: precisely timed delivery of electrical stimulation to both sides of the heart that optimizes the beating action of the lower chambers (ventricles). Leads are tiny insulated wires that connect implantable cardiac devices with the chambers of the heart.

The "silent epidemic" of heart failure affects nearly 5 million Americans and causes more hospitalizations than all forms of cancer combined. FDA approval of the implantable Medtronic InSync® Cardiac Resynchronization System last August marked a significant advancement in the treatment of heart failure, and InSync clinical studies have demonstrated dramatic improvements in quality of life, exercise capacity and heart function.

The Attain OTW lead is used with the InSync system and also with the Medtronic InSync® ICD system, which offers both cardiac resynchronization and defibrillation. Medtronic expects FDA approval of the InSync ICD in the next few weeks. The InSync ICD is specifically designed to sense from the right ventricle only, preventing inappropriate shocks from double counting due to bi-ventricular sensing.

"Cardiac resynchronization is very much an individualized therapy because every patient's heart is different," said Bruce L. Wilkoff, M.D., director of cardiac pacing and tachyarrhythmia devices, The Cleveland Clinic Foundation. "The Attain OTW lead lets me choose among more cardiac veins and access them more easily. This allows me to navigate to the left ventricle and place the electrode in the precise position to achieve the best result."

Because each patient's anatomy is unique and heart failure can result in cardiac remodeling (change of shape), left-heart lead delivery can be challenging, requiring a variety of leads and delivery tools. With its small lead body size (4 French) and distal curves designed for increased steerability and stability, the Attain OTW lead is intended to allow implanters to maneuver it into tortuous anatomies and through small and medium-sized cardiac veins.

The Attain OTW lead conforms to the IS-1 pacing connector standard, simplifying future replacements of the pulse generator. In addition, the Attain OTW lead has a 93 percent implant success rate and very low dislodgement rate. Also, the Attain OTW is the only lead of its kind for left-heart pacing that can be delivered with both a guide-wire and a stylet – a feature that allows physicians to use the technique with which they are most familiar, increasing their ability to successfully deliver therapy in most patients.

"The Attain OTW lead is another important tool for physicians and it further positions Medtronic as the industry leader in offering the broadest suite of heart failure products," said Ursula Gebhardt, vice president, Medtronic Cardiac Rhythm Management's heart failure business. "Heart failure is the only major cardiac disorder that is increasing in prevalence, and Medtronic is committed to delivering new therapies to significantly improve patient well-being."

The outside diameter of the Attain OTW left-heart lead is the same size as that of the wire in a large paperclip. Its steroid-eluting capability is designed to stabilize electrical performance. In addition, the tip contains an exclusive silicone seal that reduces the entry of bodily fluids into the center lumen.

The Medtronic Attain family of left-heart leads and accessories also includes:

- Attain LV Model 2187 and Attain CS Model 2188, commercially released outside the United States in August 1998, and in the United States in August 2001 with the InSync cardiac resynchronization system.
- Attain Side-Wire Model 4191, commercially released outside the United States in June 2000.
- Attain SD Model 4189, commercially released outside the United States in November 2000, and currently under U.S. clinical evaluation.
- Attain LDS Model 6216 and Attain Access Model 6218 left-heart delivery systems, designed to facilitate rapid coronary sinus cannulation and cardiac vein selection in left-heart lead procedures.

Medtronic, Inc., headquartered in Minneapolis, is the world's leading medical technology company, providing lifelong solutions for people with chronic disease. Its Internet address is www.medtronic.com.

Any statements made about the company's anticipated financial results and regulatory approvals are forward-looking statements subject to risks and uncertainties such as those described in the company's Annual Report on Form 10-K for the year ended April 27, 2001. Actual results may differ materially from anticipated results

EXHIBIT E